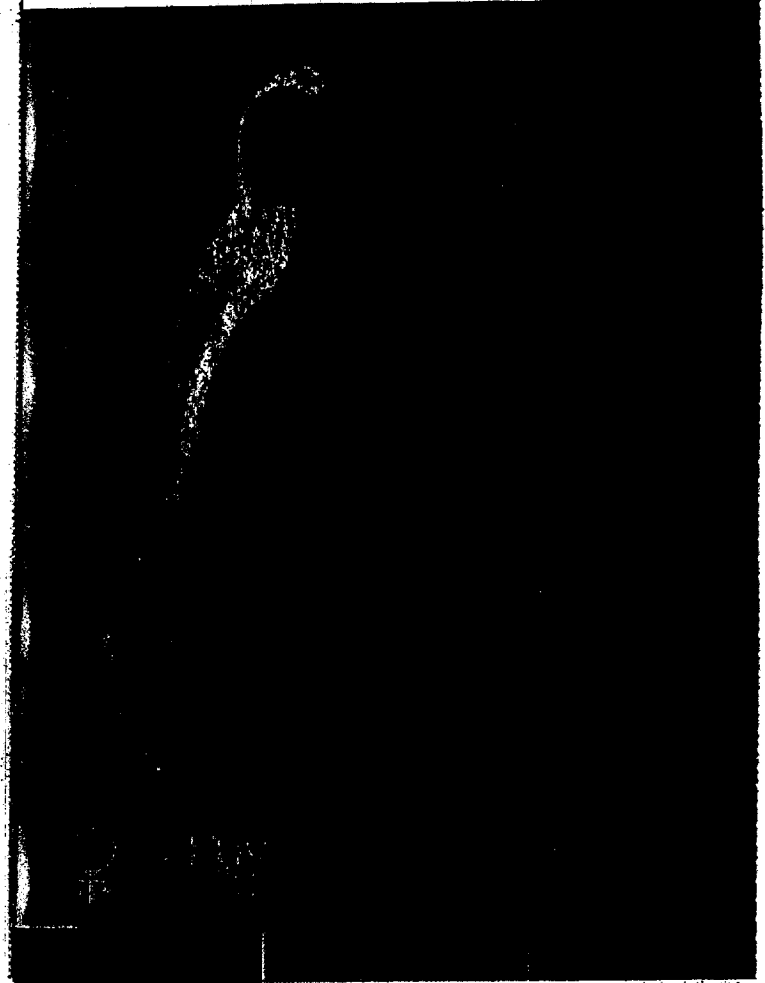


PROSTALAC® HIP
(Prosthesis of Antibiotic-Loaded Acrylic Cement)
**TEMPORARY
PROSTHESIS SYSTEM**



HUMANITARIAN DEVICE: AUTHORIZED BY FEDERAL LAW AS A SHORT-TERM TOTAL HIP REPLACEMENT (THR) IN PATIENTS WHO NEED A TWO-STAGE PROCEDURE TO TREAT A CONFIRMED INFECTION OF THEIR THR AND WHERE VANCOMYCIN AND TOBRAMYCIN ARE THE MOST APPROPRIATE ANTIBIOTICS FOR TREATMENT OF THE INFECTION BASED ON THE SUSCEPTIBILITY PATTERN OF THE INFECTING MICRO-ORGANISM(S). THE EFFECTIVENESS OF THIS DEVICE FOR THIS USE HAS NOT BEEN DEMONSTRATED.

WHAT IS THE PROSTALAC® HIP TEMPORARY PROSTHESIS SYSTEM?

The Prostalac® Hip Temporary Prosthesis System is used in patients who have infection in their hip following total hip replacement surgery. The system has a metal core hip stem combined with an outer layer that is made from bone cement. The bone cement has the antibiotic drugs tobramycin sulfate and vancomycin hydrochloride mixed together at the time of your surgery. There is also a metal hip ball and a plastic hip cup in the Prostalac Hip System.

WHAT IS THE PROSTALAC HIP SYSTEM USED FOR?

The Prostalac Hip Temporary Prosthesis System is used for two functions: 1) to allow you to move about (without putting all of your weight on your hip) during the time that the temporary implant system is in place (approximately three months) and 2) to carry antibiotic drugs to the area where the infected implant was taken out. The Prostalac Hip Temporary Prosthesis System will then be replaced with a permanent total hip replacement that will be cemented into place.

Prostalac Hip Temporary Prosthesis System

WHEN WOULD THE PROSTALAC HIP SYSTEM NOT BE USED?

There are times when the Prostalac Hip Temporary Prosthesis System will not be used. The reasons for not using the Prostalac Hip System are: poor nutrition; poor immune system (for example, due to other medications or medical conditions like diabetes); poor bone quality; poor muscle; nerve and/or circulation in the infected leg; all of the infected hip replacement parts cannot be taken out; cannot confirm that there is an infection; the infection can not be treated by the antibiotic drugs of vancomycin and tobramycin; the patient is sensitive (allergic) to the antibiotic drugs of vancomycin and tobramycin; the patient has an infection in another place besides the hip; or hip infection is not caused by the total hip replacement.

WHAT COULD GO WRONG WITH THE SURGERY?

There are problems that might happen in any type of surgery. Those problems could be, for example:

- blood clots
- heart problems
- blood pressure problems
- problem with the anesthesia
- nerve damage
- wound problems
- pain
- skin infection
- blood loss

WHAT COULD GO WRONG WITH THE PROSTALAC HIP SYSTEM?

You may have problems with the Prostalac Hip surgery such as shortening of the leg; problems getting the hip implants in or out; dislocation of the implants; breakage of the implants; or fracture of some of the bones.

With the Prostalac Hip System, you might also have a reaction to the antibiotic drugs treating the infection that may require that the Prostalac Hip be removed early; the infection might not respond to the chosen antibiotic drugs; all of the parts from the previous implant might not be removed making chances of continued infection higher (in which case the

Prostalac Hip Temporary Prosthesis will not be implanted); regulation of the dose or time of the antibiotic drugs given at the site might be difficult; or the bone cement might lose strength.

WHY SHOULD YOU CHOOSE THE PROSTALAC HIP PROSTHESIS?

You can move about while the Prostalac Hip Temporary Prosthesis is implanted and your infection is being treated systemically.

WHAT CAN YOU EXPECT WITH THE PROSTALAC HIP PROSTHESIS?

Before Surgery: You should discuss with your doctor any physical or mental conditions that you have. You should be sure that you understand what you will and will not be able to do when you have the temporary system put in.

During surgery: The infected hip implant, bone cement and all other damaged bone and tissue will be removed and the entire area will be thoroughly cleaned. The Prostalac Hip Temporary Prosthesis system will then be put in. There might be a need for some wires, plates, screws and/or rods to make the temporary system stronger.

The motion of your hip will be thoroughly checked before the hip joint area is closed.

After surgery: You will need to be seen by your doctor for regular check-ups and for x-rays. You will also have fluid removed from your hip joint to check to see if the antibiotic drugs are helping the infection. When the infection has cleared, the temporary system will be removed and your permanent hip implants will be cemented into place. The Prostalac Hip Temporary Prosthesis System will be removed within three months after it was put in. You must follow your doctor's instructions about protecting the amount of activity and weight that you place on the Prostalac Hip Temporary Prosthesis System.

WHAT SHOULD YOU REMEMBER AFTER SURGERY?

- Do not do heavy work.
- Do not perform sports activities.
- Stay away from places where you could fall.
- Do not use alcohol or drugs in large amounts.
- Do not gain weight.
- Do not walk without some form of assistance.

WHAT ARE YOUR OTHER TREATMENT CHOICES?

There are four other treatments that have been used to treat infected hips. Based on the results of long-term use, two of those treatments are no longer used. The two remaining choices that you have in addition to the Prostalac Hip Temporary Prosthesis System are: 1) single-stage surgery where the infected hip implant is removed and a new permanent hip implant is put in and 2) two-stage surgery where the infected hip implant is removed and a new hip implant is put in once the infection has cleared.

Single-Stage Surgery

With single-stage surgery, there is a chance that all of the infected implants and parts do not get removed. This could cause further infection. There is also a chance that the antibiotic drugs in the bone cement do not stop the infection; the type and dose of the antibiotic drugs are wrong; you have a reaction to the antibiotic drug and the implant would have to be removed. The strength of the bone cement may be less and the implant could become loose. The doctor is not able to use bone grafts, non-cemented or press-fit hip implants with this surgery choice.

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Prostalac Hip Temporary Prosthesis System

With single-stage surgery, you have only one surgery and therefore you have a shorter hospital stay and it takes less time to recover. You will be able to move about more quickly. There is less chance for scar tissue and tissue adhesions to form.

Two-Stage Surgery

With the two-stage surgery choice, you will not be able to move about freely until the infection has cleared and the permanent hip implant is put in. Sometimes you might have to have traction to be sure that your hip is in the right position. Because you are not able to move about, the following things could happen: blood clots, pressure sores, loss of bone quality or nerve damage.

With two-stage surgery, more antibiotic drugs can be used for a shorter amount of time and additional cleaning can be done to the infection site. Many times beads or spacers containing antibiotic drugs are placed in the space where the infected hip was removed to help clear the infection. The doctor will be able to use bone grafts, noncemented or press-fit hip implants with this surgery choice.

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Prostalac Hip Temporary Prosthesis System

HOW IS THE PROSTALAC TEMPORARY HIP SYSTEM SURGERY PERFORMED?

Before Surgery:

- You will be tested to determine whether vancomycin and tobramycin are the most appropriate antibiotics for treatment of your infection based on removing fluid from the hip joint and at least three blood samples will be checked.
- X-rays will be taken.
- The doctor will decide on the correct size of the implants for your surgery.

During Surgery:

- A cut is made to open the infected hip joint.
- Tissue is moved so that the infected hip can be dislocated and the hip cup is exposed. Fluid will be removed from the hip joint to check the type of infection.
- All of the implants, cement and other material (i.e., plates, screws etc.) are removed.
- The hip cup area is thoroughly cleared of any cement pieces, soft tissue or other materials to allow for a good fit of the temporary implants.
- The hip (femoral) area is then prepared to accept the proper size and shape Prostalac Hip Temporary Stem. This area is also cleared of any cement pieces, soft tissue or other materials.

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Prostalac Hip Temporary Prosthesis System

- One or more batches of bone cement with antibiotic drugs are prepared and put in the hip cup area. The single size Prostalac Cup is properly positioned into the prepared cemented cup area.
- The proper temporary hip stem mold is chosen and is filled with bone cement that has been combined with the chosen antibiotic drugs. The metal core stem is immediately inserted into the bone cement mold. Some of the extra bone cement mixture might be placed on the neck of the hip stem. The cement is allowed to set. The mold is opened and the Prostalac Hip Prosthesis device is removed.
- The Prostalac Hip Temporary Stem is then put in the hip (femoral) canal and tapped into place.
- All areas are cleaned.
- The hip head is then tapped into place on the stem.
- The head is put into place in the prepared hip cup space.
- Adjustments are made for proper positioning of the implants.
- The surgical area is closed.

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Prostalac Hip Temporary Prosthesis System

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.
For more information, visit our web site at www.allaboutarthritis.com



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